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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,594	12/12/2003	Charles L. Brooks	18525/04051	1737

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CALFEE, HALTER & GRISWOLD, LLP
1110 FIFTH THIRD CENTER
21 EAST STATE STREET
COLUMBUS, OH 43215-4243

EXAMINER

TSAY, MARSHA M

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 05/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/735,594

Applicant(s)

BROOKS ET AL

Examiner

Marsha M. Tsay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2005.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 19-21 is/are allowed.
- 6) ☒ Claim(s) 1-18 and 22-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

This Office Action is in response to Applicant's response, received February 7, 2005. Claims 1-26 are pending and under examination.

Priority date is December 13, 2002.

Applicants are asked to correct claim 1 from being an "original claim" to a "currently amended claim." Claim 1 was amended in Applicants' instant amendment, however, it is still labeled as an original claim.

Withdrawal of Objections and Rejections

The objection to the disclosure as having minor informalities is withdrawn.

The rejection of claim 19 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn.

The rejection of claims 23 and 24 under 35 U.S.C. 103(a) as being unpatentable over Kinet et al. (1996 J. Biol. Chem. 271(24): 14353-14360) in view of Fuh et al. (1995 J. Biol. Chem. 270(22): 13133-13137) is withdrawn.

New Rejections

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-18, 22-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is drawn to a iii) region where a replacement of an amino acid chosen from A, V, L, I, P, F, W, M, G, S, T, C, Y, N, Q, K, R, H in amino acids 160-173 of the instant human prolactin amino acid sequence is replaced with an amino acid chosen from D and E. The residues 160-173 do not contain all of the amino acids from the group of replacement amino acids that Applicants have listed. Therefore, there is insufficient antecedent basis for this limitation in the claim.

Claims 2-8, 13-18, 22-26 are included in this rejection because they are dependent on claim 1.

Claim 9 is drawn to at least one replacement mutation comprising replacing an amino acid chosen from G, S, T, Y, N, and Q, with an amino acid chosen from A, V, L, I, P, F, and M. Claim 9 is dependent on claims 1-2. Applicants have amended Claim 1 such that the replacement of an amino acid in region iii) is limited to D and E. Claim 9 is therefore, indefinite, because it is unclear from which region or residue the replacement mutation is taking place. The instant claim does not specify that the replacement mutation is in regions i) or ii), therefore, it can also refer to region iii), in which case there is no basis for the A, V, L, I, P, F, and M amino acids since claim 1 has limited the replacement mutation to amino acids D and E.

Claim 10 is included in this rejection because it is dependent on claim 9.

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Claim 11 is drawn to at least one replacement mutation comprising replacing an amino acid chosen from K, R, and H, with an amino acid chosen from A, V, L, I, P, F, and M. Claim 11 is also dependent on claims 1-2. As explained above with claim 9, claim 11 is also indefinite because it does not specify from which region or residue the replacement mutation is taking place. Therefore, there is no basis for the A, V, L, I, P, F, and M amino acids since claim 1 has limited the replacement mutation to amino acids D and E.

Claim 12 is included in this rejection because it is dependent on claim 11.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, are rejected under 35 U.S.C. 102(b) as being anticipated by Goffin et al. (1994 J. Biol. Chem. 269(51): 32598-32606). Goffin et al. teach a modified human prolactin molecule with the replacement E110A (p. 32599, methods; claim 1, 2).

Maintenance of Objections and Rejections

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-18, 22-26 are again rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims are drawn to a modified human prolactin molecule wherein the molecule comprises at least one mutation in region i), ii), and/or iii). The mutation(s) is selected from the replacement, deletion, or insertion of amino acids in region i), ii), and/or iii). The specification discloses working examples of some mutated human prolactin molecules, (p. 66 section [0188]), and disclose experiments that assess their activity. However, it is not known what type of activity, if any, that might result from the modified human prolactin molecule of the instant claims. As written, the instant claims are drawn to deletion, replacement, and/or insertion mutations of a human prolactin molecule; however, it is unknown what type of activity the modified human prolactin molecule will exhibit from these various mutations.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 13-14, are again rejected under 35 U.S.C. 102(e) as being anticipated by Chen et al. (US 20040127407A1). Chen et al. teach a modified human prolactin molecule with a deletion mutation at G49 (SEQ ID NO.7; claim 1, 13, 14).

Applicants assert that the Chen et al. reference is directed to G129R fusion proteins and the absence of G49 in Figures 11A (SEQ ID NO.7) and 11B is a typographical error. Applicants' point to Figure 1B and Figure 1F which also recite the G129R fusion protein sequence but includes the G49 residue. Applicants cite the C.C.P.A. case of *In re Harry Louis Yale*, 434 F.2d 666, 168 U.S.P.Q. 46 (1970) to support the instance when a typographical error does not place the public in possession of a claimed invention. Examiner acknowledges Applicants' arguments. However, in the instant reference, Chen et al. disclose the embodiment that in general, both the DNA and protein molecules of the invention can be defined with reference to "sequence identity" (p. 6, [0056]). Chen et al. disclose most preferred molecules have at least 90%, more preferably at least 95%, sequence identity (p. 6, [0056]). Therefore, the amino acid sequence of SEQ ID NO.7 with the G49 deletion mutation as depicted by Chen et al. is still embodied by the invention and as disclosed, does not necessarily warrant a typographical error.

Claims 19-21 are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is 571-272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

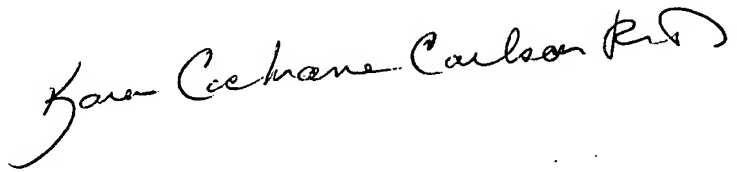
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in cursive script that reads "Karen Cochrane Carlson" followed by a stylized monogram or initials.

April 29, 2005

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER